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national cancer program

report of the national cancer advisory board

1980

Submitted to The Secretary of the Department of Health and Human Services for simultaneous transmittal to the President of the United States and to the Congress

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health
National Cancer Institute

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NIH Publication No. 81-2271
January 1981

In accordance with the provisions of the National Cancer Act of 1971 (P.L. 92-218) and the amendments of the Act of 1978 (P.L. 95-622) this report of the National Cancer Advisory Board (NCAB) for the year 1980 is presented to the President of the United States and to the Congress.

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July 17, 1980

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1

Introduction

Cancer continues to be the number one health concern of the American people. There is no other disease known to mankind which causes such great physical and psychological suffering to the patient and patient's relatives, friends, and loved ones.

The direct economic burden of cancer to the American people conservatively exceeds $20 billion per year. The anxiety, stress, pain, and suffering to the average citizen cannot be measured by material means.

The National Cancer Advisory Board, in fulfillment of its role in advising the Director of the National Cancer Program and the National Cancer Institute, studies and recommends programs designed to control and prevent cancer. These programs are aimed at applying present knowledge, increasing our knowledge of the disease itself, and determining its causes in our society.

During the past year, the Board worked to learn in detail about the funding, programs, and functions of the National Cancer Institute in a number of areas. This year the Board made special efforts to become more informed about the contract programs of the National Cancer Institute. The Board spent a full day of the May meeting at the Frederick Cancer Research Center, maintained under the largest contract of the institute. In addition, Dr. Vincent T. DeVita, Jr., then the Institute's Acting Director, requested that the Board review and make recommendations to him and his staff on the future status of the six largest contracts in the Cancer Control Program.

Due to budgetary and personnel constraints, the first meeting of the Board held during the past fiscal year was in October 1979, replacing the meetings previously held in September. In addition to hearing detailed descriptions of each of the divisional programs of the National Cancer Institute, the Board learned of the results of the reorganization of the National Cancer Institute begun while Dr. Arthur Upton was the Director.

Two new members of the President's Cancer Panel were named: Dr. Joshua Lederberg, president of Rockefeller University, who became chairman, and Dr. Bernard Fisher of the University of Pittsburgh.

Finally, the National Cancer Advisory Board during the past year has consolidated some of its previous action in developing specific objectives and functions for each of its subcommittees. These are listed in appendix 3.

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National Cancer Institute Program Reviews

During the NCAB meeting of November 1979, the directors of the four program Divisions of NCI presented the latest developments in their programs. These reviews were initiated to keep the Board up-to-date on NCI-supported research.

The first review was presented by Dr. Vincent DeVita, Director of the Division of Cancer Treatment (DCT). Dr. DeVita explained the operation of DCT, emphasizing the role of the Board of Scientific Counselors (BSC) and describing the division's grant and contract review and budget processes.

The chairman of the Board of Scientific Counselors, Dr. John E. Ultmann, who is director of the Cancer Research Center at the University of Chicago, reviewed the involvement of the BSC with the programs and staff of the division. One of the newest of these programs supports research on biological response modifiers and received $13.5 million in the NCI budget for 1980.

One of the BSC's subcommittees advises DCT on this new program. Chairman of the Subcommittee on Biological Response Modifiers, Dr. Enrico Mihich, who is director of the department of experimental therapeutics, Roswell Park Memorial Institute, described the mechanism of action and types of such agents, tests for reactivity, and the division's initial project to support production of interferon for extensive testing.

Dr. Gregory O'Conor, director of the Division of Cancer Cause and Prevention (DCCP), emphasized that prevention of cancer, from the points of view of etiology and intervention, is the basic approach

to research in his division. The scientific disciplines applied to such research include pharmacology, immunology, behavioral modification, epidemiology, carcinogenesis, and nutrition. He pointed out that since the reorganization of NCI, the primary mechanism for extramural support for research has switched from large contracts to grants, and that a Board of Scientific Counselors, a new type of review group for this division, is now systematically reviewing the intramural programs for the first time. This thorough review also includes the DCCP programs carried out at the Frederick Cancer Research Center. Dr. George Todaro, chief of the Laboratory of Viral Carcinogenesis, spoke on transforming genes derived from cellular gene sequences, and Dr. Roswell K. Boutwell, professor of oncology of the McArdle Laboratory for Cancer Research, University of Wisconsin, spoke on the present status and future prospects of research on tumor promotion.

Dr. Alan Rabson, director of the Division of Cancer Biology and Diagnosis (DCBD), described the organization and programs of DCBD, focusing on research on cancer diagnosis. He also explained the review of intramural, grant- and contract-supported research by the division's Board of Scientific Counselors and Program Advisory Committee.

Several investigators spoke on the subject of recombinant DNA, one of the promising new areas in cancer biology. Dr. Maxine Singer, chief of the Laboratory of Biochemistry, discussed some of the ways the division is using recombinant DNA techniques to study a variety of problems, and introduced several of her colleagues in turn. Dr. Peter Howley, chief of the Viral Oncology and Molecular Pathology Section, Laboratory of Pathology, explained how the development of recombinant DNA techniques has made possible extensive studies of papilloma viruses. Dr. Douglas R. Lowy, senior investigator in the Dermatology Branch, discussed experiments with animal leukemia and sarcoma retroviruses done in collaboration with Dr. Scolnick's Laboratory of Tumor Virus Genetics, DCCP, and the RNA Recombinant Research Unit in the National Institute of Allergy and Infectious Diseases. The final speaker was Dr. Igor B. Dawid, chief of the Developmental Biochemistry Section, Laboratory of Biochemistry, who described protein synthesis and structure in Drosophila.

Dr. William D. Terry, acting director of the Division of Cancer Control and Rehabilitation, briefly summarized the budget for 1979, pointing out that grants and contracts awarded in the program areas of prevention, detection, treatment, community outreach, and rehabilitation research totaled $67,086,000. Because the Cancer Control Program was undergoing reorganization as a part of the NCI reorganization, a program review was postponed. However, Dr. Terry pointed out that the division has supported a multifaceted program which focuses on:

(1) Identifying, evaluating, and planning the applications of innovative, practical methods of cancer control.
(2) Developing demonstration programs to promote the use of effective cancer control methods by the nation's health professionals.
(3) Developing training resources for educating health professionals in the use of cancer control intervention.
(4) Developing methods of encouraging beneficial attitudes and life styles as they relate to the control of cancer with emphasis on hard-to-reach populations.
(5) Providing mechanisms for organizing the Nation's resources for an effective, coordinated attack on specific cancer control problems.

Dr. Terry also reviewed the Cancer Centers Program. He has been acting director of the program since February 1978, when it was moved from the Division of Cancer Research Resources and Centers to the Office of the Director, NCI.

The purpose of the Cancer Centers Program is to facilitate research activities with relevance to cancer. The mechanism for accomplishing this is the cancer center support (core) grant, which results from investigator-initiated applications that receive an initial peer review by an NCI committee of outside advisors and a final review by the Board.

Dr. Terry distributed a brochure entitled, "Guidelines for the Cancer Centers Support Grant Program of the National Cancer Institute," which describes: (1)

The Cancer Centers Program, including the types of cancer centers, NCI support for cancer centers, and grant review procedures; and (2) the cancer center support grant, which includes such items as allowable direct costs, application format, review criteria, reporting requirements, and publications. He also distributed a list of laboratory and clinical research centers and comprehensive cancer centers together with fiscal data for these centers.

Dr. Harry Eagle, director, Cancer Research Center, Albert Einstein College of Medicine, New York City, then reported on the role and the importance of the core support grant to the activities in his center, classified as a Laboratory and Clinical Investigation Center, and Dr. Albert H. Owens, director, Johns Hopkins Oncology Center, Baltimore, Maryland, gave a similar report in regard to activities in his Comprehensive Cancer Center.

Dr. Terry and Dr. William Shingleton, chairman of the NCAB subcommittee on centers, presented revised guidelines for the recognition of comprehensive cancer centers. These guidelines clarify and replace the original 10 requirements developed by the Board in 1973. Board members adopted the guidelines with some modifications (appendix 1).

In January 1980, Mr. J. Paul Van Nevel and members of his staff reported on activities of the Office of Cancer Communications (OCC), Office of the Director. Mr. Van Nevel, associate director for cancer communications, described the great increase in the activities of the OCC over the past 5 years. These activities include public inquiries by mail and by phone, requests for publications dealing with various aspects of cancer, and questions from the press.

Two OCC staff members described some of the newer information and educational projects, designed to disseminate information as mandated by the National Cancer Act. Elaine Bratic, chief of the Information Projects Branch, reviewed the breast cancer information program, and Bernard Ellis, program director for smoking and occupational activities, reviewed information activities related to smoking and to cancer in the work place.

3

NCI Reorganization and Personnel Changes

Reports of the division directors in the previous section reflect some of the changes brought about by the reorganization of NCI, begun in 1978. In the first phase, program management was separated from grant management and from grant and contract peer review, and the use of contracts for research support was curtailed.

In October 1979, Dr. Upton explained the last phases of the reorganization, based to a large extent on the findings and recommendations of two advisory task forces. The Task Force on Control and Resource Programs, chaired by Dr. William Terry, reviewed the possible integration of programs dealing with resources, centers, and control activities. The Task Force on Prevention, chaired by Dr. Robert Hoover, explored the possibility of establishing a new division to concern itself solely with activities in cancer prevention and screening.

The following recommendations were accepted by the Institute and were submitted to the Secretary, HHS, for approval:

(1) *Control, Centers, and Resource Programs*

The Division of Cancer Control and Rehabilitation (DCCR) will be abolished as such. In its place, there will be established a new division as yet unnamed. This new division will encompass and include:

a. All components, programs, personnel, responsibilities, and activities of the Division of Cancer Control and Rehabilitation.

b. The Cancer Centers Program, including the Cancer Centers

Branch and the Research Facilities Branch, currently in the Division of Cancer Research Resources and Centers (DCRRC).
c. The Training and Education Branch, including the Research Manpower Branch and the Clinical Manpower Branch currently in DCRRC.
d. The Organ Site Programs Branch, including the Bladder, Large Bowel; Prostate, and Pancreas Programs, currently in DCRRC.

Dr. Terry, in consultation with the Management Policy Branch, will prepare a detailed plan for the internal organization structure of the new division.

(2) *Cancer Prevention*

The division directors and the acting director, DCCR, were asked to review their programs with respect to ongoing activities, opportunities, needs, and proposed new initiatives in cancer prevention and to report to the Director, NCI, on their plans and recommendations to strengthen the programs in question. Pending these reports, the divisions' ongoing and planned research programs together with the National Toxicology Program, are expected to meet the responsibilities of the Institute in the important area of cancer prevention.

The new division, in addition to programs identified above, will be responsible for:
a. Expediting the application of research findings through the development of practical measures for the prevention or early detection of cancer.
b. Conducting appropriate studies to ensure the validity and timeliness of prospective interventions intended to prevent cancer.
c. Evaluating and refining cancer prevention strategies to assure maximum benefit to the largest possible population, with the least risk and cost.
d. Developing close liaison with: cancer centers; public and professional education organizations; public health groups and agencies; labor organizations; trade and professional associations; and regulatory agencies, in order to foster communication, information exchange, and cooperation.
e. Collaborating closely with all NCI divisions and offices, other NIH Institutes, and other national and international research organizations.

(3) *Extramural Activities*

a. The Division of Cancer Research Resources and Centers will be renamed the Division of Extramural Activities and will include functions of the Research Analysis and Evaluation Branch, the Grants Administration Branch, the Grants Financial Data and Analysis Branch, and the Review and Referral Branch.
b. The division director, in conjunction with the Management Policy Branch, will prepare detailed organization plans and functional statements for this division.
c. Dr. Thomas King served as director of the Division of Extramural Activities until his resignation August 1 to return to the faculty of Georgetown University. Dr. William Walter was named acting director until a permanent successor to Dr. King is named.

These decisions complete the process of reorganization initiated last year. No further organizational changes are foreseen at this time, pending reports from division directors on prevention-related activities and plans.

In December 1979, Dr. Upton, Director of NCI since July 1977, left the Institute to become professor and chairman, Department of Environmental Medicine, New York University Medical Center. Dr. DeVita, director of the Division of Cancer Treatment, was named Acting Director of NCI in January and appointed as Director in July. In January 1980, he gave his first report to the Board.

In October 1979, Dr. Guy Newell, deputy director of NCI and acting director before Dr. Upton was appointed, left the Institute to join the University of Texas System at Houston as professor of epidemiology and director of cancer prevention at the M.D. Anderson Hospital and Tumor Institute.

In the Division of Cancer Treatment, Dr. John S. MacDonald became associate director for cancer therapy evaluation and Dr. David Pistenma became chief of the Radiotherapy Development Branch in the Cancer Therapy Evaluation Program. Dr. Odvar Nygaard, professor of radiology, Case Western Reserve University, joined the staff for 1 year. He will participate in the development of a

comprehensive research plan on the biomedical effects of radiation.

Dr. Diane J. Fink, associate director for Medical Applications of Research, NCI, also serves as coordinator for the Diet, Nutrition, and Cancer Program, and smoking and health activities. Dr. Joseph Fraumeni, chief of the Environmental Epidemiology Branch in the Division of Cancer Cause and Prevention has been named acting associate director for the field studies and statistics program. Dr. Fraumeni will continue as chief of the Environmental Epidemiology Branch for the present. Ms. Lorraine Kershner, Office of Cancer Communications, has been promoted to senior science writer.

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National Cancer Program Authorization

Throughout the year, Drs. Upton and DeVita reported to the Board on legislation authorizing the National Cancer Program. Current authorization is in effect through September 30, 1980. Bills to extend the authorization for three years were introduced in both the House and the Senate.

The Board also discussed a proposal that would eliminate NCI's budget bypass authority; abolish the President's Cancer Panel; authorize appointment of NCAB members and the NCI Director by the Secretary, HHS, rather than by the President; and make several other changes in the National Cancer Program. The Board, through its Working Group on Board Activities and Agenda and Board discussions, registered opposition to such changes.

National Cancer Institute Budget

The NCI budget for fiscal year 1980 reached the $1 billion mark, $63 million more than the 1979 budget. Dr. Frederick Seitz, in his report to the Board as chairman of the Subcommittee on Planning and Budget, explained that the $63 million is earmarked for the following projects:

National Toxicology Program ..... (28 additional positions included)	$23.0 million
Stipends for National Research Service Awards	$ 6.7 million
Biologic Response Modifiers	$13.5 million
Research Projects (R01, P01)	$18.2 million
Management and Support Costs ..... (includes NIH Management Fund)	$ 1.6 million
	$63.0 million

Dr. Seitz reported that the President's budget for fiscal year 1980 was only $937 million, the same as the 1979 budget. This figure was included in the 5-year budget projections reviewed by the subcommittee in May 1979. However, $63 million was added to the FY 1980 NCI budget as a result of Congressional action, thereby eliminating the need to reprogram funds.

This 1980 revised level was included as a base for the 1981 budget submitted to the Office of Management and Budget in September. The subcommittee reviewed the 1981 submission and the 5-year projections.

The Board discussed the adverse effect on the Centers Program of level funding for core support in 1980. The Board approved a

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National Cancer Institute Training Programs

motion to call the Director's attention to the fact that core support was not increased in 1980 and to keep this matter in mind at the next budget review. The Board also approved a motion stating that a reexamination of the spending plan would be appropriate to assure that all reasonable measures are taken to avoid jeopardizing core support.

Dr. Seitz, as well as Drs. Joshua Lederberg and Henry Pitot, attended the NIH annual program review, which covered the budget for 1982-1984. Discussions centered on the impact of the 1981 budget on future years and the intention of the NIH administration to stabilize the number of grant-supported research projects, (R01's, P01's, and young investigator awards) in years when the budget just barely keeps up with inflation. Under these circumstances, some programs may have to be substantially decreased or phased out. Topics of discussion of special interest to NCI included the future of cancer centers, decreases in the Control Program, and the intramural, Organ Site, Construction, Training, and Clinical Trials Programs. Dr. DeVita requested the NCAB to help NCI set priorities during this period.

Dr. Barney C. Lepovetsky, chief of the Research Manpower Branch, Division of Cancer Research Resources and Centers, discussed proposed guidelines for applicants and reviewers in regard to NCI support of research training programs. The guidelines were proposed to fill a need for an explicit policy regarding cancer orientation. The policy adopted by the Board (appendix 2) confirms the propriety of NCI support for research training in the scientific disciplines that are important for cancer research. The policy states that excellent training in a discipline(s) must be the primary criterion by which a training program is evaluated. The policy recognizes that such excellent training can be provided in settings where cancer research is not emphasized; however, the policy requires that trainees in NCI-supported programs receive a thorough orientation toward cancer and an understanding of the relation of their scientific disciplines to cancer.

Dr. Lepovetsky also discussed the NIH program of National Research Service Awards for short-term training. The program is designed to support students in health professional schools for up to 3 months in biomedical research. After lengthy discussion during which it was established that NCI already provides considerable support for short-term training within the Clinical Cancer Education Program, the Board concluded that NCI should participate minimally in the newly established NIH program. The Board also advised that this minimal participation include only programs relevant to a primary discipline of cancer. These conclusions were partially stimulated by the prospects of a very tight budget year.

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National Cancer Institute International Affairs

It was reported to the Board that in June 1979, a delegation of U.S. cancer scientists visited Hungary. The visit to Budapest marked the beginning of NCI's efforts to develop a cancer program as part of an umbrella Science and Technology Agreement signed with Hungary in 1979.

Dr. Frederick P. Li of the Clinical Epidemiology Branch went to Peking in 1979 under the auspices of the National Academy of Sciences. In conjunction with an agreement between the People's Republic of China and the United States, Drs. Arthur Upton, Henry Pitot, John MacDonald, Robert W. Miller, and James L. German III, visited the People's Republic of China.

Environmental Carcinogenesis and Prevention

The Board continued to hear from representatives of other government agencies with cancer-related activities. In October, Dr. Charles Carter, scientific director, National Institute of Environmental Health Sciences (NIEHS) and Dr. Joseph Rodricks, deputy associate commissioner for science, Food and Drug Administration (FDA), described their cancer-related testing and basic science programs. NIEHS and FDA are two of the eight agencies, including NCI, that comprise the National Toxicology Program formed to carry out several of the mandates of the 1978 amendments to the National Cancer Act that deal with environmental carcinogenesis.

Aware of the need to call attention to problems of environmental carcinogenesis, the Board, several years ago, formed the Subcommittee on Environmental Carcinogenesis. In January, the subcommittee met to discuss the final wording of its charter and members accepted it unanimously (appendix 3).

Dr. Gerald Wogan, chairman of the subcommittee, explained that this redefinition of the subcommittee's role followed the completion of a statement drafted by the subcommittee on the relationship of bioassay data to risk assessment in humans. In the course of preparing this statement, the subcommittee questioned its role in developing such documents and concluded that it was not their responsibility. They then decided that they would use the draft statement on risk assessment as a guide in identifying and defining important issues relevant to environmental carcinogenesis. In addition, the issuance of the Interagency Regulatory Liaison Group and other Government-sponsored, cancer-related documents obviated the need for the subcommittee to prepare its own statement.

In discussing long-range agenda items, subcommittee members agreed on the need for a visit to the Frederick Cancer Research Center to review the carcinogenesis program. This would be the first step in carrying out the charge of monitoring NCI programs in environmental carcinogenesis and advising the Board on matters of program balance. A second item for discussion would be the impact of the National Toxicology Program on NCI with respect to the amount of money allotted by the Institute and the effect on research activities as a result of personnel shifts.

Dr. Donald Luecke, acting chief of the Special Programs Branch, Division of Cancer Cause and Prevention, NCI, reported on an initiative in cancer prevention intended to foster the simultaneous development of quality research and education programs in epidemiology and biostatistics as well as other related biomedical sciences. A draft of guidelines for preventive oncology academic awards in epidemiology/biostatistics was distributed to the Board. These awards were initiated in fiscal year 1980.

Staff of NIH and NCI appeared before Congress to discuss several areas of environmental carcinogenesis, including the issues of biomedical effects of low-

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Report of the National Cancer Advisory Board Subcommittees on Construction and National Organ Site Programs

level radiation; aging; and diet and nutrition in cancer. Dr. Upton said that he was pleased to announce at the nutrition hearing, that in the May (1979) round of grant applications, NCI funded 17 grant applications in the field of nutrition, which represented 36 percent of all the approved nutrition applications. Senator McGovern, chairman of the Senate Subcommittee on Nutrition, said however, that he was deeply concerned about peer review and was afraid that the composition of the study sections and their general approach to proposals in the nutrition area had led them to view these matters with a bias to the detriment of nutrition. He announced that he was asking the General Accounting Office to conduct a full-scale review of the peer review system at NIH.

A. Construction Subcommittee

During fiscal year 1979, the National Cancer Institute received 14 grant applications for NCI participation in development of cancer research facilities. These requested $30.6 million for construction and/or renovation of 263,941 gross square feet of research space. Of these, 12 applications were approved and recommended for funding, and of these, 7 were awarded funds. This was the maximum number that could be funded within the limitations of the NCI construction budget of $12 million. From the applications that were approved and funded, 127,284 square feet were developed for cancer research, distributed as follows:

Clinical Care and Research Areas	17.9%
Clinical Support Areas	3.8%
Research Laboratories	
Standard Labs (38.4%)	
Biohazard Labs (7.1%)	
	45.5%
Research Animal Space	11.3%
Other Laboratory Support	3.5%
Education/Training	3.2%
Cancer Control	0.4%
Cancer Program Admin. and Support	6.0%
Facilities Maint. and Service Areas	4.4%
Other	4.0%
TOTAL	100.0%

An analysis of the expenditures of NCI construction dollars indicates that for each Federal dollar awarded to an applicant institution, approximately one dollar was generated from non-Federal sources. These data are based on awards made when the grantee matching requirement was only 25 percent from non-Federal sources. Since February 1978, the matching requirement has been 50 percent.

A major activity carried out this fiscal year at the request of the National Cancer Advisory Board, through its Subcommittee on Construction, was an evaluation of the current and future funding needs for cancer research facilities to meet research priorities and in particular to upgrade facilities for biohazard containment and for research animal facilities to meet existing safety codes and federal regulations. Several sophisticated surveys were conducted by the staff of the Research Facilities Branch, DCRRC, NCI. The evaluation addressed the funding needs in four categories:

Biohazard containment facilities
Animal facilities
"Standard" research laboratories
Clinical research facilities

In summary, these surveys identified the need for approximately an additional $25 million per year in NCI budget support for fiscal year 1980 through fiscal year 1985 to meet these needs. A multiyear sustained increase in budget level for the construction program appears to be required to meet these needs.

See appendix 3 for information on the subcommittee's objectives and functions.

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Board and Panel Membership and Functions

None of the Board members' terms expired in 1979. However, Dr. Victor Alexander, medical officer in the office of technical support, Occupational Safety and Health Administration, U.S. Department of Labor, replaced Mr. Anson M. Keller, special assistant to the assistant secretary for occupational safety and health, as alternate to ex officio member, the Honorable Ray Marshall, Secretary of Labor.

In December 1979, the President appointed Dr. Joshua Lederberg, president of the Rockefeller University, as chairman of the President's Cancer Panel for 1 year, and Dr. Bernard Fisher, professor, department of surgery in the School of Medicine at the University of Pittsburgh, as a member of the Panel through 1982. They replace Mr. Benno C. Schmidt and Dr. Paul A. Marks. Dr. Elizabeth C. Miller, professor of oncology and associate director, McArdle Laboratory for Cancer Research, University of Wisconsin Medical School, is the third member of the Panel whose appointment expires in 1980.

The Working Group on NCAB Activities and Agenda was very active this year and made many suggestions that were carried out or will soon be carried out. As a result of discussions by the working group and full Board, Board meetings this year were held for 3 instead of 2 days, allowing more time for review of grants. In the future, a full day will be reserved for grant review at each meeting where grants are to be approved. To further reinforce this effort to improve grant review, the Special Actions Subcommittee

B. National Organ Site Programs Subcommittee

During the past year, the subcommittee reviewed the scientific accomplishments and management of the National Bladder Cancer Project. It was noted that the bladder project has provided a focal point for coordinating the efforts of laboratory and clinical scientists toward meaningful investigation of the early diagnosis, cause, management, and course of bladder cancer. The headquarters staff has been effective in managing this Project and in stimulating activity beyond the resources of the project. It has been equally effective in communicating with the biomedical community.

The National Pancreatic Cancer Project was also reviewed. This project has been successful in stimulating an increase in pancreatic cancer research and in recruiting new investigators. They have established effective communication between researchers and practitioners. Communication with appropriate programs of the NCI has also been effected. A number of scientific articles based on research funded through the National Pancreatic Cancer Project have been published.

The subcommittee plans to continue its review of National Organ Site Projects during the next year. During this time, it is anticipated that the subcommittee will review the National Large Bowel Cancer Project and the National Prostatic Cancer Project.

The subcommittee reviewed the procedures by which it discharges its responsibilities for monitoring the activities of National Organ Site Projects and for reporting to the National Cancer Advisory Board. See appendix 3 for information about the subcommittee's objectives and functions.

was enlarged to include all Board members except ex officio members. The Board will continue to examine other ways it can better carry out its function of grant review as charged by the National Cancer Act.

The working group requested a report to the full Board on activities of NCI's Office of Cancer Communications. The working group also requested a report on the pending legislation for the National Cancer Program authorization, which they discussed in detail at their December meeting. Both presentations were made at the January 1980 meeting of the NCAB.

Other suggestions made by the working group include a review of the Frederick Cancer Research Center and a site visit to the center, reports on the Cancer Control Program, on guidelines for cancer center support (core) grants, on the Diet and Nutrition Program, and on the National Toxicology Program. These presentations are being prepared and will be presented at future Board meetings.

Other topics discussed by the working group included:

(1) Restructuring the subcommittees of the Board by defining or redefining the charge of each subcommittee and assigning Board members to the newly charged committees.
(2) The NCAB Annual Report for 1979 and the content and form of future reports. For future reports, a writing committee composed of the chairman of each Board subcommittee and a few additional Board members will be charged with preparing the annual report. In addition, because 1981 will be the 10th anniversary year of the passage of the National Cancer Act, the suggestion was made that a special anniversary issue of the report be written. That proposal will be discussed at a future Board meeting.
(3) The legislative process, as explained by Dr. Burke Zimmerman, director of the Division of Legislative Analysis of NIH. (Dr. Zimmerman made a similar presentation to the full Board at the October meeting.)
(4) The need for greater input by the Board in regard to appointments to the Board.
(5) Closer coordination among NCI and other Government regulatory agencies, particularly occupational programs with NIOSH and consumer products with EPA and OSHA.
(6) Proposal to schedule the Board meetings so that on the first day, the meeting begins at 8:30 a.m. with an open session followed by a closed session at 3 o'clock for the meeting of the Subcommittee on Special Actions. As it stands now, the Subcommittee on Special Actions meets first and the open session begins in the early afternoon.

In October, Board member Dr. G. Denman Hammond, who is associate dean of the School of Medicine, University of Southern California, reviewed advances in the treatment and cure of cancers of children; the major types and frequency of pediatric cancers; observations of acute leukemia in children; and factors influencing prognosis in acute lymphocytic leukemia, undifferentiated leukemia, and solid tumors. Dr. Hammond's report emphasized the remarkable successes achieved by research on treatment of childhood cancer.

As an outstanding example of the dramatic results of modern therapy of a previously fatal disease, the mother of the family in the picture on the following page is a case in point.

In March 1959, at the age of 13 years, 7 months, Jennette Hubbard was referred to the Children's Hospital of Los Angeles, where the diagnosis of acute lymphocytic leukemia was confirmed by all the customary tests. She was treated with prednisone, methotrexate, and 6-MP used sequentially in courses of 6 weeks each. She remained on this therapy, with occasional skips of prednisone therapy because of acne, for 7 years. She attained a complete clinical and bone marrow remission during her first course of therapy and has remained in complete, continuous remission thereafter. During 1963, she appeared to be having a clinical relapse; however, it was confirmed that she had infectious mononucleosis and not a recurrence of leukemia. Her therapy was discontinued, she had bone marrow examinations at intervals, all of which were normal. She had been on continuous chemotherapy for 7 years, and has had no antileukemic treatment for 14 years.

Jennette married Mr. Larry Hall in 1966. She is now aged 34 and has four children. Her first natural

daughter, Ellen, was born 11 years ago when Jennette was 23. A natural son, Jerry, is now aged 6 and was born when Jennette was 28. She and her husband also have adopted two children, their son Jesse, now 9 years of age and their daughter, Lisa, now 15 years old. Jennette is an active housewife with a part-time job.

While such successes with this disease are not universal, they are not exceptional. Today half or more of patients with acute lymphocytic leukemia are treated successfully and many of these are living perfectly normal lives completely free of a disease which not many years ago was fatal in every case within a relatively short period.

L-R: Jesse, 9; Lisa, 15; Larry; Jennie; Jerry, 6; Ellen, 11.

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Recommendations and Actions of the NCAB for 1980

The following resolution was presented to the Board in October 1979 and unanimously passed:

Whereas, the National Cancer Act Amendments of 1977 provide that the Director of the National Cancer Institute, if authorized by the National Cancer Advisory Board, may obtain the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications.

BE IT RESOLVED, that in accordance with Section 404(b) (1) of the Public Health Service Act, as amended, the Board authorizes the Director of the National Cancer Institute to appoint not more than 151 experts or consultants under such agreement as the Director shall have with the Civil Service Commission. The Director shall report each year to the Board on the operation of this authority.

(2) In November 1979, the Board adopted revised guidelines, with some modifications, for recognition of a Comprehensive Cancer Center. The new guidelines are listed in appendix 1.

(3) As an indication of the Board's concern about the effects of the 1980 budget level for core support of cancer centers, the Board approved the following two motions in November, each with one dissent:

a. To call to the attention of the NCI Director the fact that core support was not increased in fiscal year 1980 and to keep this matter in mind at the next budget review.

b. To state that the Board feels it appropriate that the spending plan be reexamined so that all reasonable measures can be taken to avoid jeopardizing core support.

(4) At the request of Board member Mr. Samuels, concerning the Board's legal rights and responsibilities in regard to contracts, NCI staff prepared a paper outlining how the Board has dealt with contracts, in the past; the Board's legal responsibilities in the contracts process; and what the Board might do in the future. The document was sent to Board members prior to the October meeting. After considerable discussion and comment concerning the document, the Board recommended that its Working Group on NCAB Activities and Agenda review the recommendations made and develop an appropriate report for presentation to the Board at a future meeting.

(5) In January, Mrs. Lasker suggested that the Board pass a motion that Dr. DeVita inquire about the proposed World Health Conference on interferon and take appropriate action.

Appendix 1

Guidelines for Recognition of a Cancer Center as Comprehensive

These guidelines describe the qualities and characteristics that the National Cancer Advisory Board (NCAB) considers essential for recognition of a cancer center as comprehensive. They will be used by reviewers to evaluate centers that are seeking recognition as new comprehensive centers and also to evaluate established centers to determine the advisability of continued recognition.

In establishing these guidelines, the NCAB does not intend that every institution participate in all possible activities relevant to cancer. For example, although one of the requirements for recognition as comprehensive is the existence of high-quality research activities, there is no requirement that *all* research areas be pursued at a given center. Rather, there is the requirement that there be high-quality activity in *some* aspects of clinical research, *some* aspects of cancer control, and *some* aspects of training, education, and information dissemination. The term "comprehensive" is intended to convey that the cancer center has high quality activities in each of these major areas, but that within any given area, the center may choose to pursue particular topics and not others.

(1) *National and Local Support*
The cancer center must have a funded cancer center support (core) grant, indicating that center activities are of sufficient quality to achieve funding from the National Cancer Program. In addition, there must be evidence of material support for center activities from the parent institution(s) and the local community.

(2) *Research Activities*
The cancer center should support laboratory, clinical, epidemiologic, and evaluative research efforts of the highest quality and should create an environment which fosters cancer-related information exchange, cooperation, and collaboration between laboratory scientists of multiple disciplines and between laboratory scientists, clinical scientists, and epidemiologists. Centers should maintain their own clinical investigative activities. Those activities should include participation in regional and/or national clinical trials related to the cancers being studied by the center in question. The center should have available the personnel and facilities to carry out high quality, diagnostic, therapeutic, and rehabilitative procedures in the interdisciplinary setting most suited to the cancers being investigated. The center should make a commitment to participate in uniform clinical data acquisition and reporting through the centralized cancer patient data system (CCPDS).

(3) *Cancer Control Activities*
The cancer center should serve an important focal point for local and regional programs designed to control cancer through research and demonstration activities in areas such as prevention, detection, diagnosis, treatment, and rehabilitation. The center should seek the active participation of all sectors of the professional and lay community in control activities.

(4) *Training, Education, and Information Dissemination*
The cancer center should serve as an important focal point for local and regional information dissemination, as well as for professional and lay education programs. Programs to assess which methods of information dissemination and education effectively modify professional and lay behavior patterns are desirable. Centers should also be actively involved in training of professional and support personnel.

(5) *Administration*
The cancer center or, in the case of consortia, the constituent institutions should have a formal commitment of support from the parent institution(s) manifested by the center director having the following: (a) primary control of space and equipment; (b) necessary control over professional and staff appointments to enable the center director to effectively direct the center and assure accomplishment of its mission; (c) control of grouped beds and ambulatory facilities for clinical cancer research; and (d) responsibility for program planning, evaluation, and implementation, preparation of budgets, and control of expenditures. In addition, the center must have an administrative structure that will assure long-term viability, efficiency of operation, and sound financial practice.

(6) *Geographic Impact*
Scientific excellence of any center is a primary consideration. The geographic location of the cancer center, however, should increase the national capability to carry out regional clinical trials, regional cancer control programs, and

Appendix 2

Research Training Grant Policy

regional training, education, and information dissemination activities. The location of other comprehensive centers and the size of the regional population with access to the center are additional factors bearing on recognition.

Cancer is a complex of diseases which will be understood only after many more years of basic and applied research in all areas of biomedical science. To assure an adequate number of gifted researchers for an effort of this breadth, the National Cancer Institute maintains a stable, long-term research training system whose scope includes all relevant clinical and nonclinical sciences. The principal criterion for funding research training projects is *quality* of the training. Implicit in the term is the requirement that a scientist training in a discipline be exceedingly well trained in *that* discipline. Secondarily, the trainee should be oriented towards cancer during the course of training so that in the future he will be able to relate the skills and tools of his scientific discipline to the ultimate understanding of cancer. So that the best and most responsive kind of training will be offered, the NCI's training system encourages each research institution to use its own unique strengths in building its cancer research training program. Some institutions will do their best with small unidisciplinary programs; others will capitalize on the diversity of their strengths and will develop excellent highly multidisciplinary programs. To assure that the NCI's research training system will continue to develop in accord with these concepts, the following policies will be followed in the review of applications and in the administration of the program:

(1) It is not mandatory that a trainee engage in research palpably related to cancer, nor that his preceptor be engaged in such research. However, the reviewers will take note of the following questions in assessing the merit of research training grant applications:

a. Will each predoctoral trainee attend a general course concerning the cause, nature, diagnosis, and treatment of cancer?

b. Are more specific courses also available to predoctoral trainees, as for instance, tumor virology, tumor immunology, etc.?

c. Will predoctoral and postdoctoral trainees attend cancer-related seminars, journal clubs, or lectures on a regular basis?

d. Will postdoctoral trainees deficient on oncologic knowledge have access to the resources mentioned in "a" and "b" above?

All trainees and fellows will be encouraged to attend one NCI-sponsored "Pathobiology of Cancer Workshop" during their training period. Research training projects embodying the above features will be deemed to show "cancer orientation."

(2) To allow the NCI to take advantage of strengths unique to each training site, applicants are to be afforded maximum freedom in shaping high-quality training projects. Therefore, the following *is permitted* as a matter of policy:

a. more than one training grant per division, college, or campus;

b. overlap in faculty, provided faculty members are not overburdened with training responsibilities to a project's detriment.

Appendix 3

Objectives and Functions of the NCAB Subcommittees

Special Actions Subcommittee

The role of the Special Actions Subcommittee has been to consider for presentation to the Board, grants judged by staff to merit special attention. Among the categories of grants reviewed are: (1) R01 applications for non-U.S. citizens in foreign countries that did not receive priorities in the upper third of approved grants but were considered on grounds of uniqueness to merit funding should the pay level reach their normalized priority; (2) domestic grants approved or disapproved by split vote of the study section; and (3) grants (R01 or P01) considered by staff to warrant a second review or a site visit before final disposition.

The Special Actions Subcommittee is informed of grants posing problems in biohazard or human subject considerations whether the applications are approved or disapproved. The application is held for corrective action before a grant is funded.

The role of the subcommittee has evolved during the past 2 years to include a central function in reviewing study section assessment of R01 grants program by program with the help of the program secretaries and supportive staff. Tumor biology, viral oncology, immunology, diagnosis and treatment, and epidemiology have been examined so far by a review of the summary sheets prepared from the study section evaluation. Two members of the subcommittee have been assigned as reviewers for each application with the charge to raise questions where a significant discrepancy exists between the priority assigned and the written critique as recorded in the summary (PINK) sheet.

This systematic reading and discussion of evaluation and program direction have provided the Board members with a closer view of both program direction and the level of original approaches to the general questions that emerge in each segment. It has also created some impressions about the difficulty experienced by investigators attempting to explore a novel approach. Almost invariably the collective conservatism of study sections is evident in the lower priority accorded new ideas with the comment that there is a "certain risk" to an interesting approach that may not work out. The highest priorities are reserved for excellent conceptual and technical proposals that pursue the lines of the discipline currently in vogue.

Subcommittee on Centers

The functional objectives of the Subcommittee on Centers are as follows:

(1) a. Review with National Cancer Institute cancer centers staff, cancer center core grant applications prior to final NCAB action.

b. Review special actions related to cancer center core grant applications brought to it by NCI cancer centers staff, and make recommendations on these special action request to the NCAB.

(2) Review and make recommendations concerning policy matters related to the NCI Centers Program, when so requested by the NCAB or director of the Cancer Centers Program of NCI. Examples of such requests are: (a) Review and make recommendations relative to the 10 criteria for a comprehensive cancer center; (b) Review and make recommendations relative to requests by applicant institutions, after a peer review site visit, to be recognized as a "comprehensive" cancer center; (c) Advise and make recommendations on other policy matters relating to the Cancer Centers Program when requested to do so by the NCAB or the director of the Cancer Centers Program of NCI.

Subcommittee on Construction

This subcommittee was originally established to deal with the extremely important construction program of the National Cancer Institute.

The subcommittee reviews with the National Cancer Institute construction staff, construction grant applications prior to final NCAB action. Special problems which arise are dealt with in the subcommittee by the establishment of appropriate recommendations for action by the NCAB. Before the end of each fiscal year, the subcommittee establishes a priority ranking of all approved construction grants for the year and makes a recommendation to the NCAB on the funding of construction grants based on the total funds available for construction during the particular fiscal year.

The subcommittee has also

assumed the responsibility for determining the achievements of the NCI construction program with the periodic publication of detailed summaries of those construction projects completed and their impact on the center with which they are associated. In addition, the subcommittee has assumed the responsibility of determining present and future needs for construction facilities to maintain the National Cancer Program as funded by the NCI. Publication of these needs and appropriate recommendations to the NCAB is a correlating function of this subcommittee.

Subcommittee on National Organ Site Programs

This subcommittee is charged with the monitoring of the specific National Organ Site Programs established by the NCAB including those on colon, bladder, pancreas, and prostate.

The subcommittee reviews the progress of the Organ Site Program yearly and reports on its status to the National Cancer Advisory Board.

The subcommittee reviews applications for support of the headquarters of each National Organ Site Program following their review by the appropriate review body.

The subcommittee also reviews applications to initiate new National Organ Site Programs at the national level.

Subcommittee on NCAB Activities and Agenda

This small subcommittee has many of the characteristics of a working group which, informally and flexibly, as well as promptly, can respond to the needs of the full Board and its chairman in facilitating the administrative operations of that body. This operation is conditioned by the following factors: The Board by statute is tasked with a wide variety of advisory, review, and approval duties with respect to the National Cancer Program. In this role, it complements rather than displaces or overlaps the expert guidance of the Director of the NCI, the staff of the NCI, the Director and relevant officers of the NIH, and the officers of DHHS. As a presidentially appointed Board, it is given statutory responsibility that requires careful and documented actions which must fit a thriftily prepared agenda, to conserve the time of the many diverse members. At the same time it has an overall task of encouraging creativity, ingenuity, initiative, and quality in advancement of the biosciences and biotechnologies that comprise biomedicine and support of public health.

Thus, the Board must take special pains to assure that it is not a mere rubber-stamp or routine-approval group, a condition which the large scope and volume of the National Cancer Program could easily cause. Accordingly, it has created this Subcommittee on Activities and Agenda to be a kind of internal conscience in seeking out and reporting to the chairman and to the Board the best ways of using the meeting time, the best topics for major attention, and the best estimates of how the required functions of the Board are being discharged. Further, it is tasked with looking ahead as to suitable succession in membership as determined by the proper agencies of Government led by the President, and of linking its activities with the Congressional legislative responsibilities to the people, so as to make the best progress in the conquest of cancer.

The subcommittee is presently paying special attention to interactions of the NCAB with other Federal and national agencies and advisory groups. This is so that the Board shall be able to coordinate, especially through regulatory and legislative activities, the best that is known to benefit the public, arising from the ongoing programs of research and development in science and technology throughout the world.

Subcommittee on Environmental Carcinogenesis

The subcommittee has responsibility for monitoring activities relevant to environmental carcinogenesis at national and international levels, including ongoing research and research needs of potential future value. The subcommittee is responsible for assessing these activities in terms of their relevance and significance to environmental causes of human cancer and related public health issues. The subcommittee also is responsible for identifying

training needs and resources related to environmental carcinogenesis. In accordance with this charge, the subcommittee advises the National Cancer Advisory Board as to the state of the art, ongoing or new programs that should be emphasized, program balance, and the role and relationship of NCI activities to the field of environmental carcinogenesis.

The NCAB Subcommittee on Planning and Budget—Functions and Objectives

Section 404(a) (9) of the National Cancer Act (as amended in 1978) calls for the Director, NCI, to prepare annually a program plan with budget projections for the ensuing 5 years. Also, section 404(a) (8) states that the Director "prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needed for the National Cancer Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Cancer Advisory Board. . . ."

The objective of the Subcommittee on Planning and Budget is to work with the NCI staff to produce a 5-year program plan and associated budgets as well as to review the annual budget proposal for the ensuing budget year which it can recommend to the NCAB for approval and endorsement. Based on this endorsement, the Director, NCI, submits the annual plan to the Secretary, DHHS, for simultaneous transmittal to the President and the Congress. The annual budget estimate is sent directly to the President.

The subcommittee achieves its objective through two major functions:

(1) At least once each year, the subcommittee meets with the NCI executive committee for a detailed program-by-program discussion and analysis in the early stages of budget formulation. Changes and revisions agreed to at this meeting are reflected in subsequent planning and budget activities.

(2) As program plans and budget are refined during the year, they are reviewed by the subcommittee at special meetings held concurrently with scheduled meetings of the NCAB.

National Cancer Program

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